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THE SAFETY AND EFFECTIVENESS OF USG-GUIDED PERCUTANEOUS ETHANOL INJECTION (PEI) IN CYSTIC THYROID NODULES

ENT

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ABSTRACT

Background: To evaluate the effectiveness and safety of USG-guided percutaneous ethanol injection (PEI) in cystic thyroid nodules.

Patient and method: This was a prospective conducted in the Department of E.N.T and Head & Neck Surgery on 20 patients with cystic thyroid swelling visiting in our OPD over a period of one year were thouevaluated history taking, general and local examination,ultrasonography,fine needle aspiration cytology,thyroid profile(euthyroid patients were taken). Usg guided 95% ethanol istillation was done and significant reduction in volume was studied at the end of 3 months follow-up period.

Result: Mean age of the patients in this study was 36.65 years range 18-51 years among them 90% were female and 10% were male patients M:F ratio 9:1. Mean volume reduction rate (%) was found 53.81 % after one month,73.97 % after two months, >90 % after 3 months of instillation of sclerosing agent and Mean volume reduction rate (%) after 3 months of re-instillation was recorded 92.39%.

Conclusion: We conclude that, in the management of benign thyroid cysts, USG-guided percutaneous ethanol injection is a cost-effective and efficient non-surgical treatment modality with higher success rates. It is a relatively safe procedure with very low or no complication rates, and has better patient tolerability.

KEYWORDS

USG-guided percutaneous ethanol injection (PEI), Volume reduction rate, benign thyroid cysts.

INTRODUCTION

Thyroid nodule, which is one of the most frequently encountered thyroid diseases and is characterized by growth of abnormal tissues into the thyroid gland. Its incidence varies among population and geographic regions. Epidemiologic studies have shown the prevalence of palpable thyroid nodules to be approximately 5% in women and 1% in men living in iodine deficient parts of the world[1].

Thyroid nodules have been classified as solid and cystic based on the anatomic structure of the lesion. Thyroid cysts with a volume of 5 ml or more may cause mechanical problems especially cosmetic defects.Simple aspiration of the cystic portion of the nodule can reduce pressure-related symptoms and cosmetic problems. Although aspiration can induce the collapse of the cystic portion, with high recurrence rate, depending on the initial volume of the nodule. Larger cystic nodules recur more frequently after aspiration than do small nodules. Simple drainage is usually not successful in either small or medium-sized cysts, with recurrence rates between 58% and 80%, depending on the size, volume and number of previous aspirations[2,3]. Large complex cysts recur rather commonly[4]. According to the American Thyroid Association and the European ThyroidAssociation, a conservative (or non-surgical) approach should be used for benign cystic thyroid nodules. Radioactive iodine ablation, a non-surgical method of treatment, is effective but requires special equipment[4]. Higher cost of laser or radiofrequency ablative procedures have been the most important disadvantages of these methods. Another option includes tetracycline instillation; however, this method has not been proven to be capable of producing any statistically significant reduction in the size of thyroid cysts[5]. Sclerotherapy using percutaneous ethanol injection (PEI) is another non-surgical procedure that has drawn attention as a therapeutic option in cystic thyroid nodules[6]. Although ethanol ablation is less satisfactory when it is used to treat predominantly solid thyroid nodules[7], ethanol ablation is useful in the treatment of cystic thyroid nodules (cystic portions > 90%), affording volume reductions of 85–98.5%.

Patients and Methods

This was a prospective study conducted in the Department of E.N.T and Head & Neck Surgery on 20 patients with cystic thyroid swelling visiting in our OPD over a period of one year after due clearance from the Institutional Ethics Committee.

Inclusion criteria:

Patients age more than 10 year (range between 18-51 years), who had single clinically palpable thyroid nodule with cosmetic or pressure symptoms also diagnosed case of solitary, cystic thyroid nodule by various modalities. Patient also give a Written consent after information.

Patientsattending ENT OPD with thyroid swelling were evaluated history taking, general and local examination,ultrasonography,fine needle aspiration cytology,thyroid profile(euthyroid patients were taken).

Exclusion criteria

Patients aged <10 years, not willing to give written consent after receiving due instructions were excluded from the study. Also, patients with previous history of neck surgery or neck irradiation, history of allergy to sclerosing agents, nursing or pregnant women, severe secondary disorders, bedridden patient and malignat thyroid swelling were not considered as a part of the study.

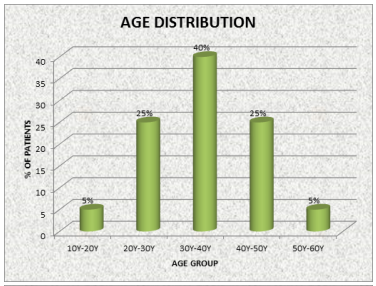
PROCEDURE:

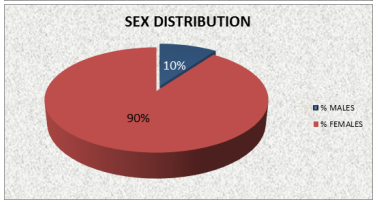
Prior to procedure pulse, temperature, blood pressure were recorded and ensured that these parameters were within normal limit. Patient was laid in the supine position with mild neck extension and the volume of the swelling was calculated prior to procedure. The volume of a cyst (except a complex cyst), was calculated by using the following formula: length × width × height × π / 6. For a complex cyst, volume was calculated as the volume of the cystic component other than solid areas. Afterthesterilisation of the working area with 70% ethanol, a 20- 22 gauge needle was inserted (without local anaesthesia) under sonographic guidance, to aspirate cystic fluid as completely as possible and then 95% ethanol was slowly (approximately 1 ml/min) instilled into the cavity to a volume ofapproximately 50%of the volume of aspirated fluid. The injection of ethanol was stopped if ethanol leaked out of the nodule or the patient complained of pain. The needle or catheter was withdrawn, gentle pressure was applied over the puncture site for 10–15 min and the patient was observed for signs of any complications.All the patients were followed at regular interval of 1 month, for 3 months. At each follow-up, the patients werere-evaluated for any side effects such as scarring and obvious reduction or increment in size. Also, an ultrasound was done to documentthe volume of cyst, intracystic fibrosis and vascularity.More than 50% reductionfrom thebaseline volume was accepted as procedural success.The effect of the therapy was presented as the VOLUME REDUCTIONRATE (volume reduction rate (%) = [initial volume – final volume after treatment] / initial volume × 100%), and each case

was classified into one of the following sixgroups:cysts with a <50% reduction in volume, 50% -60% reduction in volume, 60%-70% reduction in volume, 70%-80% reduction in volume, 80%-90% reduction in volume and>90% reduction in cyst size.95% Ethanol was re-instilled (after 3 months of follow-up) if there was no significant reduction in the cyst volume (i.e. reduction by ≥50% of the initial volume). Such patients were subsequently called after 1 month, to ascertain the results. If even after 3 months of re-instillation, significant improvement could not be obtained, then patient was advised for surgery.

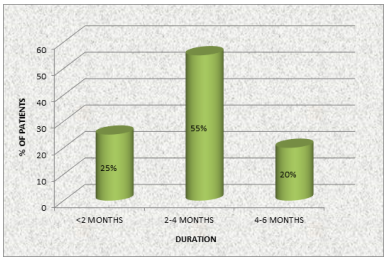
Results

The study was conducted on 20 patients of euthyroid non-neoplastic solitary cysts of thyroid gland. After one month, two months and three months of follow-up, results obtained are as follows.Most of the patients belonged to age group of 30 – 40 years.Mean age of the patients included in our study was 36.65 years and ranged between 18years-51years of age. 90% of the patients were females, and only 10% patients were males in our study.

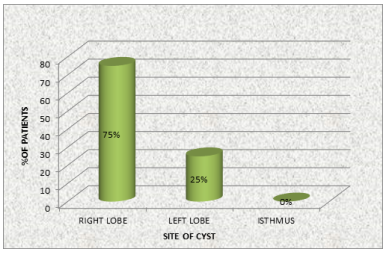




Maximum number (55%) of patients presented in our OPD with their complaints between 2-4 months duration, 25% patients presented within 2 months duration & 20% patients presented between 4-6 months duration of their disease.



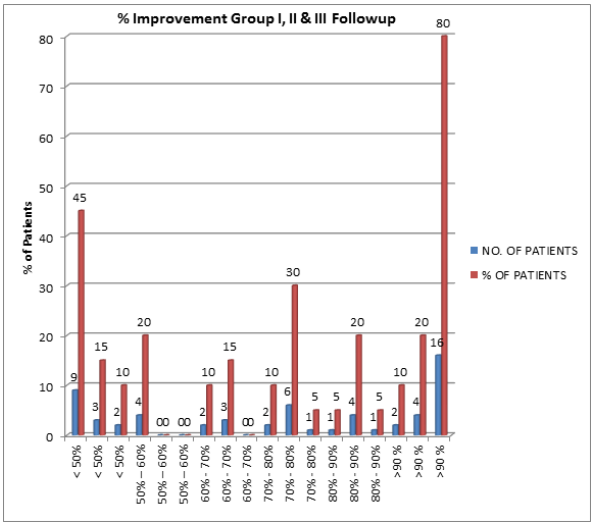
Majority of patients (75%) in our study had their cyst in right lobe of thyroid & 25%, in left lobe of thyroid, 0% in the isthmus.



We found that most of the patients (40%) had their cyst volume in the range of 3.6-4.0 cm^3, 35% patients had volume of 3.1- 3.5 cm^3, 15% reported volume of 4.1-4.5 cm^3, while 5% show reduction in volume after 1 month, 2months and after 3months of instillation of 95% ethanol.

The graph shows reduction in volume after 1 month, 2 months and after 3 months of instillation of 95% ethanol.

Reduction in volume of cyst in subsequent months of follow-up were calculated as VOLUME REDUCTIONRATE (volume reduction rate [%] = [initial volume – final volume after treatment] / initial volume × 100%).



SIGNIFICANCE OF REDUCTION:-

Table No. 8: shows significance of reduction in size.

S. No.	Comparision Of Reduction In Size	Statistical Significance
1	Pre-procedure size (3.605 cm^3) – 1st month followup size (1.665 cm^3).	**P<0.05**
2	1st month follow-up size (1.665 cm^3) – 2nd month follow-up size (0.9385 cm^3).	**P<0.05**
3	2nd month follow-up size (0.9385 cm^3) – 3rd month follow-up size (0.442 cm^3).	**P<0.05**
4	Pre-procedure size (3.605 cm^3) – 3rd month follow-up size (0.442 cm^3)	**P<0.05**

Statistical significance was calculated using paired t-test.

The reduction in volume of cyst was found to be significant after instillation of sclerosing agent. Further reduction continued even in subsequent visits and the resulting volume was significantly less than the previous volumes.

Discussion

Although US-guided PEI is not a method commonly used to treat symptomatic thyroid cysts, it has proven to be a suitable and effective alternative to surgery. A 2013 review by ***Gharib et al***[8] showed that in large centers with experienced hands, these minimally invasive approaches appear effective and safe and PEI therapy is recommended for recurrent benign thyroid cysts.

Various literatures document, several methods for treating benign cystic thyroid nodules, among these methods, simple fine-needle aspiration has been shown to have a high recurrence rate of 58%[9, 10]. Various sclerosing agents such as ethanol, tetracycline, OK-432 or isotonic saline are used to treat thyroid cystic nodule and all are effective but the effectiveness of ethanol sclerotherapy seems superior to all. Management of thyroid cysts usingsclerosing agent was first reported by ***Edmonds et al***[9]in 1987. Later ***Rozman et al***[10]in 1989**,** introduced percutaneous ethanol ablation for cystic thyroid nodules.The proposed mechanism of sclerotherapywas,epithelial cell dehydration and protein denaturation. This is followed by coagulative necrosis, reactive fibrosis and small vessel thrombosis, which results in the obliteration of the cyst.According to ***Chang HS et al***[11]**, *Bilal Cetin et al***[12] 4th decade is the most common age of presentation of thyroid nudule and in this study most of the patients lying in the group 30-40 years (40%).

In this study, 90% were female patients and just 10% were males, suggesting higher prevalence of thyroid cyst in females. Female predominance of thyroid cysts was also noted by other authors in related studies. In this study, it was found thatright lobe ofthe thyroid was more affected (75%) by the cyst, but the related data was not found. Pre-procedure volume in our study ranged between 2.1- 4.5 cm^3

with average volume 3.605 cm^3. 75% patients had their cyst size of 3.0-4.0 cm^3. After 1 month of sclerotherapy, average volume reduced to 1.665 cm^3 recording 53.81% improvement.55% patients reported significant reduction in their cyst size just after 1 month of sclerotherapy, of which 10% patients showed >90% improvement. After 2 months of follow-up, mean volume reduced to 0.9385 cm^3 and showed volume reduction rate of73.97 %. Now 85 % patients significantly improved and 20% had their volumes reduced by > 90%. Further reduction in cyst size was noticed after 3 months as mean volume became 0.442% and demonstrating 87.73 % reduction rate. This time 90% patients showed significant reduction i.e. 80 % patients had near complete resolution of cyst (>90% reduction in cyst size) and 10% patients had 50-90% reduction rate. ***SR Jayesh et al*** [1]in 2009 performed a similar study over 15 patients. Ethanol was used as the sclerosing agent and was instilled under sonographic guidance and their study has comparable results to this study.

In a study performed by***Bennedbaek and Laszlo Hegedus***[13] (2003), on 66 patients with recurrent thyroid cystic nodule, using ethanol (instillation followed by emptying) and isotonic saline as sclerosing agents, an overall success rate of 82% was reported in the ethanol group, while the saline group showed only 48% reduction rate. Higher success rates were recorded in our study (90%) which could be due to difference in selection criteria of thyroid cysts and procedure.

Kim DW & Rho MH et al[14] in 2005 studied and compared the therapeutic success rates in aspiration and nonaspiration techniques and they showed it was almost similar 96% and 93% respectively, concluding that percutaneous ethanol injection without aspiration of ethanol-mixed fluid is the preferable method of treatment of benign cystic thyroid nodules from the perspective of both the physician and the patient.

While in a study by ***Cho YS et al***[15]in 2000 and ***Sung JY et al***[16]in 2008, the non-aspiration approach was used and thereported success rates ranged from 68 %by Cho YS et alto 100% by Sung JY et al.

In 2013, ***Bilal Cetin et al***[12] retrospectively evaluated medical files to present the results of 28 patients who were treated by Doppler ultrasound guided percutaneous ethanol injection (PEI) into benign cystic thyroid nodule. They reported 88.5 percent success rate with single application ofPEI. Reinstallation in unsuccessful cases, increased the success rate to 92.9 percent.

Their study shows inferior result than this study (100% success rate after 2nd instillation), which could be explained by the fact that they used aspiration method of sclerotherapy but in our study,non-aspirationmethod of sclerotherapywas used.

It was noted in our study that cyst of < 2.5 cm^3 showed mean reduction rate> 95%, while cysts of> 4 cm^3 had mean reduction rate of 71%. Henceit can be said that smaller cysts show better results than the larger ones.

Conclusion

we conclude that, in the management of benign thyroid cysts, USG-guided percutaneous ethanol injection is a cost-effective and efficient non-surgical treatment modality with higher success rates. It is a relatively safe procedure with very low or no complication rates, and has better patient tolerability.

DECLARATIONS

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Conflict of interest: no
Ethical approval: yes

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